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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,787	02/04/2001	Kelly Knappe	398824	7067

1095 7590 10/01/2003

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

SCHEINER, LAURIE A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/01/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/776,787

Applicant(s)
Knape et al.

Examiner
Laurie Scheiner

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 26, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above, claim(s) 3, 4, 15-21, 28, 29, and 36-39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 30, and 33 is/are ~~allowed~~ **Free of the Prior Art of Record.**
- 6) ☒ Claim(s) 1, 2, 5-8, 10-14, 22-27, 31, 32, 34, 35, and 40-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 & 12 6) ☐ Other:

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Applicant's election of Group II (claims 1, 2, 5-14, 22-27, 30-35 and 40-48) is acknowledged. Claims 3, 4, 15-21, 28, 29 and 36-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14. Applicants' comments with respect to their traversal are not persuasive. Applicants fail to distinctly and specifically point out the supposed errors in the restriction requirement. That is, applicants have merely offered (independent of the reasons given for the restriction requirement) their position on the grouping of the claims. That is, an actual direct response to the specific reasons for restriction have not been set forth. The traversal is essentially on the ground(s) that rejoining Groups I and II will not create a search burden. Groups I and II will not be combined as requested since the Groups are respectively limited to different compositions. Regarding applicant's reasons for the traversal, it is asserted that a search burden is not the sole consideration for determining restriction between inventions.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

The invention appears to employ novel viral strains. Since the isolates are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed deposited strains are not fully disclosed, nor have all the sequences required for their construction been shown to be

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publicly known and freely available. The enablement requirements of 35 USC 112 may be satisfied by a deposit of the viral isolates. The specification does not disclose a repeatable process to obtain the microorganisms and it is not apparent if the DNA sequences and/or microorganism are readily available to the public. Accordingly, it is deemed that a deposit of these strains should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited two bovine viral strains under ATCC accession numbers VR-874 and PTA-3000, but there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strains have been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney or record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

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Claims 5, 7, 8, 10-14, 22-24, 31, 32, 34, 35 and 40-48 are rejected under 35 U.S.C.

§ 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 22, 25-27, 44, 45, 47 and 48 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mostl et al. (ZENTRALBLATT FUR VETERINARMEDIZIN. REIHE B, (1988 Apr) 35 (3) 186-96).

Mostl et al. clearly teach an oil-adjuvanted vaccine of inactivated bovine rotavirus and coronavirus, as well as Scourguard 3 (R) which contains live attenuated bovine rotavirus and coronavirus comprising an inactivated *E. Coli* K99.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 24, 40, 41-43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mostl et al.

Mostl et al. as set forth above.

Mostl et al. fail to teach the specific routes of administration, adjutants, etc., as claimed.

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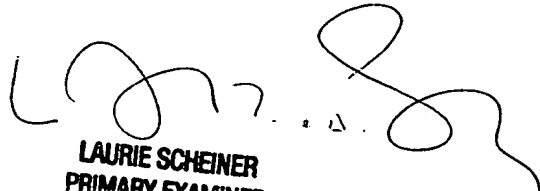
However, limitations drawn to specific reagents and means of administration represent obvious modifications related to establishing optimal reaction conditions. Such parameters in this art would be determined by routine experimentation. In re Aller et al, 105 USPQ 233 (CCPA - 1955)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.


Laurie Scheiner/LAS
September 17, 2003


LAURIE SCHEINER
PRIMARY EXAMINER